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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(54) Title: SOFT GAS PERMEABLE CONTACT LENS HAVING IMPROVED CLINICAL PERFORMANCE</p> <p>(57) Abstract</p> <p>A hydrophilic soft gas permeable contact lens having substantially improved clinical performance by the provision of a sufficient higher proportion of hydroxy acrylic units to silicon units in the lens surface layer, as compared to that existing in the lens core, by the surface treatment of the lens, such as by reacting of the lens surface with polyols and base or acid or by radiation treatment of the base lens to graft, deposit or coat thereon hydroxy acrylic units.</p>			

* See back of page

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SOFT GAS PERMEABLE CONTACT LENS
HAVING IMPROVED CLINICAL PERFORMANCE

BACKGROUND OF THE INVENTION

This application is a continuation-in-part of prior applications, Serial Nos. 07/407,261, filed September 14, 1989; 07/132,174, filed December 14, 1987 (which in turn is a continuation-in-part of prior application Serial No. 001,149, filed January 7, 1987); and 07/381,587, filed July 18, 1989.

The present invention relates to contact lenses, and more particularly to hydrophilic soft gas permeable contact lenses having improved clinical performance.

Among the most important properties and requirements of contact lenses are substantial permeability to oxygen (commonly referred to as DK), and a highly wettable and deposition-resistant surface.

The development and use of plastic materials and compositions for contact lenses has been the subject of much attention over the years.

Among the first such developments was the so-called hard lens utilizing the hard plastic polymethylmethacrylate (PMMA). However, this material does not exhibit a significant degree of oxygen permeability and has very poor surface wettability characteristics. The art then progressed to soft lenses based upon poly 2-hydroxyethyl methacrylate (poly HEMA), a material having significantly better oxygen permeability and surface quality than the

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hard PMMA plastic. Nevertheless, these characteristics were still not as high as desirable or necessary, and lenses of this type often resulted in serious problems of corneal staining, swelling, ulcers, thickness and infection.

Somewhat more recently, based upon better understanding of the corneal requirement of substantial oxygen permeability, the art proposed the use of so-called hard gas permeable (HGP) lenses composed of either of two types of plastic materials, acrylic silicone or acrylic fluorosilicone. See, e.g., U.S. Patent No. 3,808,178. Generally, the oxygen permeability of HGP lenses can progressively be increased with increasing amounts of the silicone and/or fluorosilicone in the composition; at the same time, however, the surface wettability of the lens becomes progressively poorer. In order to overcome this problem, it is known to incorporate a relatively large amount of methacrylic acid (MAA), an ionic material, into the formulation, resulting in the lens surface being negatively charged to a certain extent. While this expedient does lead to improved surface wettability, the negatively-charged surface has a very high absorptivity leading to serious deposition problems. As a consequence, the HGP lens is of only limited potential.

Most recently, hydrophilic soft gas permeable (SGP) lenses have been developed based upon compositions containing, e.g., a polymerizable vinylic siloxane monomer and a hydrophilic vinylic monomer. See, e.g., U.S. Patent Nos. 4,136,250; 4,182,822; 4,261,875; 4,343,927; 4,426,389; 4,486,577; 4,605,712; 4,711,943 and 4,837,289. The SGP lenses of this type, which generally have a water content of from about 25 to 75% by weight, have excellent oxygen permeability and hydrophilicity. Surprisingly, however, the clinical performance of SGP lenses, including

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functional (i.e., on the eye) wettability, deposition resistance, dehydration resistance and/or comfort, is very poor, making such lenses unsuitable for extended wear.

Thus, notwithstanding the advances made to date, there still exists a need for plastic contact lenses of the SGP type which not only possess a high degree of oxygen permeability, but also exhibit excellent clinical performance, such as functional wettability, deposition resistance, and comfort, thus making the lenses suitable for extended wear. The foregoing is the principal object of the invention.

SUMMARY OF THE INVENTION

This and other objects are achieved in the present invention by the provision of a soft gas permeable contact lens, composed of the polymerization product of compositions containing a polymerizable vinylic siloxane monomer and a hydrophilic vinylic monomer, having on the lens surface a proportion of hydroxy acrylic monomer units to silicon units sufficient to provide an SGP lens having the requisite high DK, softness and rebound elasticity, and which at the same time possess a high degree of clinical performance, thus rendering the lenses eminently suitable for long-term extended wear.

The requisite sufficient proportion of hydroxy acrylic monomer units to silicon units on the lens surface can be attained by surface treatment of the lens in order to increase hydroxy acrylic monomer units and/or to reduce the silicon units on the surface. In preferred embodiments of the invention, the surface treatment is carried out either by reaction on the lens surface with a polyhydric alcohol (polyol) and/or base or acid, or by radiation treatment of the lens to graft, deposit or coat hydroxy acrylic monomer units on the surface thereof.

It should be noted that the present invention differs significantly from prior art practices related to the provision, or attempted provision, of a hydrophilic surface on a hydrophobic lens. Thus, hydrophobic lenses are known in the art which are made of silicone rubber, a cross-linked polysiloxane, such as illustrated in U.S. Patent No. 3,228,741. These hydrophobic lenses are highly oxygen permeable but are extremely poor in functional wettability, deposition resistance and comfort, and also exhibit a mysterious tight lens syndrome. It is known in the art to seek to improve the functional wettability of such lenses by provision of an ultrathin coating of hydrophilic polymer. See, e.g., U.S. Patent Nos. 3,854,982; 3,916,033; 3,925,178; and 4,143,949. Generally these efforts have not in any event proven successful. One reason is because the silicone rubber lens is rather rigid, and as a consequence an ultrathin (i.e., Angstroms level) hydrophilic coating is easily rubbed away during routine cleaning cycles, with the result that the lens soon re-exhibits the poor wettability, poor deposition resistance, discomfort and tight lens syndrome characteristic of silicone rubber hydrophobic lenses. Provision of thicker layers of hydrophilic polymer on the lens to resist rubbing off is impractical, since oxygen permeability of the lens is substantially reduced and since the differences between the refractive index of the silicone rubber and the thick hydrophilic polymer coating become such as to result in a highly undesirable lens.

In the present invention, the lens per se is a hydrophilic SGP lens containing a substantial amount of water (e.g., generally at least 25% by weight) such that its surface, in contrast to the silicone rubber lenses, is already highly hydrophilic and no apparent need would exist to provide a hydrophilic polymeric surface coating thereon as is taught with respect to hydrophobic lens

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materials. In the present invention, it has surprisingly been found that the SGP lenses, even though having highly hydrophilic surfaces, nevertheless can still be very poor in clinical performance, and that this problem can be overcome by providing on the surface of the SGP lens a ratio of hydroxy acrylic units to silicon units which is sufficient to bring about significant clinical improvement.

Also in contrast with the treatment of hydrophobic silicone rubber lenses, it is found that the criteria employed in improving wettability of those lenses by hydrophilic monomer coatings is not correlatable to bringing about improved clinical performance in the hydrophilic SGP lenses to which the present invention is directed. For example, for hydrophobic lenses, acceptable wettability has been determined based upon contact angle (see, e.g., Col. 7, lines 13-16, of U.S. Patent No. 4,143,949), resulting in findings that coatings based upon amide monomers (e.g., N-vinylpyrrolidone) are quite effective in improving wettability (see, e.g., Example 1-2 of the above patent). In contrast, however, in the context of the hydrophilic SGP lenses of the present invention and particular those of preferred center thickness of from 0.05 to 0.08 mm, such amide group-containing monomers are quite ineffective in improving the clinical performance of the SGP lenses.

Accordingly, the findings and techniques of the present invention would not have been derivable or predictable from the known practices regarding improving the wettability of hydrophobic silicone rubber lenses.

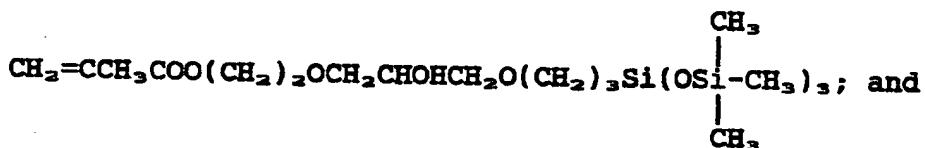
DETAILED DESCRIPTION OF THE INVENTION

The basic teachings and formulations and techniques regarding formation of silicone-based SGP lenses are known

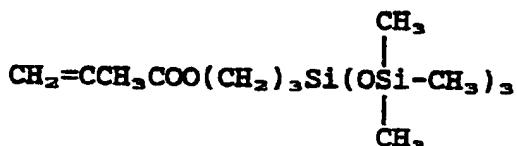
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in the art, as reflected in the earlier-mentioned patents, the disclosures of which are expressly incorporated herein by reference. The SGP lens is formed from the polymerization product of compositions containing at least one polymerizable vinylic siloxane (PVS) monomer, and at least one hydrophilic vinylic monomer. The polymerizable vinylic siloxane monomer contains at least one polymerizable vinylic group such as acrylic, styrenyl or vinylic group, at least one polysiloxanyl group, and at least one linkage connecting these two groups; thus, for example:

tris(trimethylsiloxy)silylpropyl-glycerol-ethyl
methacrylate



δ -tris(trimethylsiloxy)silylpropyl methacrylate
(also sometimes referred to hereinafter as TSM)



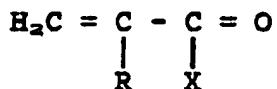
Hydrophilic vinylic monomers suitable for use in SGP lens compositions along with the PVS include, for example, N,N-dimethylacrylamide (NNDMA), 2-hydroxyethyl methacrylate (HEMA), glyceryl methacrylate (GMA), N-vinyl pyrrolidone and the like.

The lenses per se are formed by lathe cutting, cast molding, spin casting, or other like known techniques.

As earlier noted, SGP lenses made according to the known formulations possess a high oxygen permeability but exhibit poor clinical performance. In the present invention, it has been discovered that by increase of the

proportion of hydroxy acrylic monomer (HAM) units, preferably HEMA and/or GMA units, to silicon units at the lens surface, the clinical performance can be substantially improved. As used herein, the units referred to are the structural monomeric units or the number of silicon atoms, including those as part of an overall copolymeric structure.

Hydroxy acrylic monomer (HAM) suitable for the practice of this invention correspond to the formula



wherein R is H or a substituted or unsubstituted alkyl, such as methyl or CH_2COOH ; and X is a radical selected from the group consisting of hydroxyalkyloxy, hydroxyalkyl amine, and hydroxy; with the alkyl being substituted or unsubstituted, and preferably selected from C_1 to C_{10} alkyls, most preferably C_2 and C_3 alkyls; and with the hydroxy on the alkyl being either a single hydroxy (e.g., as in 2-hydroxyethyl methacrylate) or multiple hydroxy (e.g., as in glyceryl methacrylate). Exemplary and preferred hydroxy acrylic monomers are:

1. 2-hydroxyethyl acrylate or methacrylate;
2. glyceryl acrylate or methacrylate;
3. ethylene glycolato ethyl acrylate or methacrylate, i.e., $\text{CH}_2=\text{CRCOO}-\text{CH}_2-\text{CH}_2-\text{O}-\text{CH}_2-\text{CH}_2-\text{OH}$
4. glycerolglyceryl acrylate or methacrylate, i.e., $\text{CH}_2=\text{CRCOO}-\text{CH}_2\text{CH}(\text{OH})-\text{CH}_2-\text{O}-\text{CH}_2-\text{CH}(\text{OH})-\text{CH}_2-\text{OH}$
5. N-hydroxymethyl, N-methyl acrylamide or methacrylamide;
6. N-2-hydroxyethyl, N-methyl acrylamide or methacrylamide;
7. N-2,3-dihydroxypropyl, N-methyl acrylamide or methacrylamide;
8. acrylic acid, methacrylic acid or itaconic acid.

As noted, the SGP lens of the invention is made from the known SGP lens compositions and, after lens formation, the lens is then treated to provide on its surface a proportion of HAM units to silicon units (e.g., by increase of HAM units and/or by decrease of silicon units) sufficient to provide improved clinical performance of the lens, such as functional wettability, deposition resistance, dehydration resistance and comfort.

One means for achieving the requisite surface proportion of HAM to silicon units is by reaction of the lens surface, preferably in the dehydrated state, with a polyol of the formula $R_1(OH)_n$ where R_1 is a substituted or unsubstituted alkyl, preferably a C_2 to C_5 alkyl, and n is an integer of at least 2, such as glyceryl methacrylate, ethylene glycol, glycerine, glycerine-glycerine, polyglycerine, or the like. The reaction is preferably carried out in the presence of a base, such as sodium hydroxide, preferably in a concentration of 0.1 to 10 mole percent based on the polyol, or an acid or acid-containing mixture, such as ethanol/sulfuric acid, the reaction being conducted to the extent that the physical properties of the base lens (e.g., strength, oxygen permeability, softness, rebound elasticity, etc.) are essentially unaffected. This reaction is intended to increase the HAM units in the surface layer by transesterification and/or to reduce the silicon units by the cleavage of siloxane bonds catalyzed by base or acid.

Alternatively, the core lens can be treated with a HAM, preferably 2-hydroxyethyl acrylate or methacrylate, by grafting, deposition or coating to the lens surface so as to provide a sufficient proportion of HAM units to silicon units at the lens surface. The grafting, deposition or coating can be carried out using known radiation-induced reactions, including reactions induced by UV,

x-ray, γ -ray, and other electromagnetic radiation, such as radio frequency, microwave and the like, electron beam radiation, including electrical discharge, and the like, with reactions induced by UV, γ -ray or electron beam radiation being preferred. The treating techniques per se that can be used in the practice of this invention are well known in the art, such as the grafting, deposition or coating cured by UV, γ -ray or electron beam, illustrated in U.S. Patent Nos. 3,916,033 and 3,854,982; coating by spin casting or cast molding of the lenses cured by radiation; or plasma treating techniques, such as those disclosed in U.S. Patent Nos. 3,925,178 and 4,143,949, as is well known in the art. The disclosures of these prior art patents are expressly incorporated herein by reference. In the preferred embodiment of the invention, the surface treatment produces on the lens surface a thin coating consisting essentially of poly(hydroxy alkyl acrylate and/or methacrylate), more preferably poly(2-hydroxyethyl acrylate and/or methacrylate).

The required sufficient proportion of HAM units to silicon units on the lens surface that produces the desirable clinical performance will vary primarily depending upon the type and amount of particular PVS and hydrophilic monomer employed. However, the sufficient proportion in the surface layer will, at any proportion, be higher than that existing in the lens body or core. Preferably, the proportion of HAM units to silicon units in the surface layer is at least 0.5. Generally, the higher the proportion the better the clinical performance of the lens, and the thicker the treated surface layer the better the durability of the lens wettability. However, the treated layer can not be so thick that the desired properties of the lens are adversely affected. The extent of acceptable surface treatment can be monitored by high resolution photoelectron spectroscopy (ESCA) or based on the clinical response as illustrated in the examples of this specification. Thus, based on the disclosure of this invention,

the sufficient proportion of HAM units to silicon units on the lens surface can easily be determined by those skilled in the art.

Although not wishing to be bound by any theory as such, it is postulated that the improvement in the clinical performance of the lens comes about, at least in part, by virtue of establishment of compatibility between the delicate corneal wetting mechanism of the eye and the composition and structure of the lens surface. The known SGP lens having insufficient proportion of HAM units to silicon units or containing too high a level of silicon units on the surface are too hydrophobic for the spreading and binding of mucin to the lens surface. Mucin is the excellent wetting agent used in the cornea and contains a certain proportion of hydrophilic sites to hydrophobic sites. With increasing amount of HAM units on the lens surface, there are provided increased sites for hydrogen bonding with the hydrophilic sites on the mucin, while reduction of silicon surface units provides fewer hydrophobic sites and thus better spreading of mucin on the lens surface. As a consequence of the preferred embodiment of the invention herein, which results in the lens surface having a sufficient proportion of HAM units to silicon units, the lens surface becomes more closely matched to, and receptive to, tear mucin. As a result, the mucin can better spread on and bind to the lens surface so as to provide the improved clinical performance. Thus, when the wetting angle of the lens is controlled to that of the corneal surface free of mucin, the best results of this invention may result.

The invention is further illustrated with reference to the following examples.

EXAMPLE 1

SGP lenses were fabricated from buttons which were made according to the formulations and procedures set forth in U.S. Patent No. 4,182,822, the starting formulation consisting of 36% (by weight), γ -tris(trimethylsiloxy) silylpropyl methacrylate (TSM) prepared according to Example 1 of the above patent, 59% N,N-dimethylacrylamide (NNDMA), and 5% methyl methacrylate (MMA) with 0.3% t-butylperoxypyvalate included as a catalyst. The formulation was placed in a Teflon tube. After deoxygenation by nitrogen for 15 minutes, the tube was sealed and the formulation was polymerized in a 40°C water bath for six hours, followed by a 100°C treatment for another six hours. The buttons cut from the rods were post-cured at 110°C under high vacuum (0.5 Torr) for six hours.

The lens can be made by the lathe technique known in the art. The hydrated lenses were extracted and conditioned in physiological saline solution for a time sufficient to insure no substantial irritation.

The lens thus made has high DK, about 4 to 5 times higher than that of the conventional poly HEMA soft lens, and contains about 50% by weight of water, and thus has softness, rebound elasticity and a highly hydrophilic lens surface. The proportion HAM units to silicon units on the lens surface is equal to zero. Clinically, the lenses were very poor in performance such as functional wettability, deposition resistance and comfort, making the lens unsuitable for extended wear.

Provision of 6% by weight HEMA in the formulation, such that the formulation comprised 36% TSM, 58% NNDMA and 6% HEMA, results in a lens having high DK, softness, rebound elasticity, a highly hydrophilic surface and a

proportion of HAM to silicon units equal to 0.15, and thus an improved SGP lens having improved clinical performance, such as functional wettability, deposition resistance and comfort as compared to the control lens above. Clinically, the lenses could be worn for up to several hours by test patients.

In the same manner, using 20% by weight HEMA, such that the lens formulation contains 36% TSM, 44% NNDMA and 20% HEMA, results in a lens having high DK, softness, rebound elasticity, a highly hydrophilic surface and a proportion of HAM units to silicon units equal to 0.5, and thus even more improved clinical performance, such as functional wettability, deposition resistance and comfort, as compared to the control lens. Clinically, the lenses could be worn continuously for up to several days by test patients, with wettability marginally unacceptable in certain circumstances.

Further increase of the HAM to silicon proportion by increase of the amount of HEMA in the composition is at the expense of TSM, and thus reduces the oxygen permeability of the lens and/or causes the formation of opaque material. As shown in the following examples, further increase of the HAM to silicon proportion can be achieved by surface treatment.

EXAMPLE 2

The lens containing 20% HEMA as made in Example 1, after being hydrated in physiological saline solution, is then extracted in isopropanol for 24 hours, followed by treatment in the dry state with glycerine (96% purity, Colgate Palmolive Co.) containing 1 mole% NaOH at 70°C for 30 minutes by stirring. The strength of the lens after the treatment was not significantly affected. The resulting lens could be used for at least weekly extended wear

by the test patients. The clinical of long term wearing on one patient showed that the lenses could indeed continuously be worn for up to 3 months for at least certain patients. Thus, the surface treatment resulted in substantially improved clinical performance.

EXAMPLE 3

A SGP lens comprising 47% (by weight) TSM, 45% NNDMA and 8% HEMA, having 38% water content, high DK, softness, highly hydrophilic lens surface and a proportion of HAM units to silicon units equal to about 0.15, was found to be unsuitable for extended wear. Clinically, the lens produced poor vision, discomfort and encountered serious deposition problems within less than four hours of wear. However, treatment of the same lens in dehydrated state by stirring the lens in a glycerine reagent (96% purity, Colgate Palmolive Co.) containing 10 mole% NaOH at 70°C for 2 hours converted the lens to one which on the same patient could be used for weekly extended wear for a three week testing period with stable vision and no observable deposition, and demonstrated a liquid layer over the lens surface.

EXAMPLE 4

According to an independent surface study (about 100 Å° surface layer) by photoelectron spectroscopy (ESCA) analysis of the lens after being treated as described in Example 3 showed that there was a reduction of about 18% silicon or about 30% siloxy group and an increase of overall carbon content from 62.5 to 65% in which the C in the CO group increased from 10.5 to 12.5% and the C in the COOR group increased from 5.3 to 6.3% after the treatment. The increase of CO and COOR content should indicate that the transesterification of glycerine occurs, i.e., the

formation of glyceryl methacrylate. The reduction of silicon units and/or the increase of glyceryl methacrylate units after the treatment increases the proportion of HAM units to silicon units which provides the substantially improved clinical performance as described above. (Note: ESCA data is the average value of the treated surface with 100 Å depth. Thus, the value right at the surface is substantially higher than those reported above.)

EXAMPLE 5

An unhydrated optically polished lens button was made according to U.S. Patent No. 4,182,822 employing 36% (by weight) TSM, 42% NNDMA and 22% HEMA, and glycerine surface treated as set forth in Example 3 herein. The button was fully hydrated in physiological saline solution, and its surface was subjected to a number of simulated cleaning cycles, each cycle involving thumb-rubbing 10 times in tap water, followed by wetting in physiological saline solution. The surface wettability to the physiological saline solution was substantially the same based on visual inspection after sixty (60) cleaning cycles, equivalent to about one years service life of the lens in weekly extended wear.

The surface of the untreated button was substantially not wettable by physiological saline solution under the same testing condition.

Although the invention has been described in connection with particular preferred embodiments, it is not intended to limit the invention to particular forms set forth, but on the contrary, it is intended to cover such alternatives, modifications and equivalents as may be included within the spirit and scope of the invention as defined by the appended claims.

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WHAT IS CLAIMED IS:

1. A hydrophilic soft gas permeable contact lens having high oxygen permeability, softness and rebound elasticity, comprised of a polymerization product of a composition comprising a polymerizable vinylic siloxane monomer and a hydrophilic vinylic monomer, and containing in its surface layer a sufficiently higher proportion of hydroxy acrylic monomer units to silicone units than exists in the lens body so as to additionally provide a high degree of clinical performance to said contact lens.
2. A contact lens according to claim 1, wherein said sufficiently higher proportion results from treatment of the surface of said lens so as to provide in said surface layer a sufficient proportion of hydroxy acrylic monomer units to silicon units.
3. A contact lens according to claim 2, wherein said hydroxy acrylic is hydroxyalkyl acrylate and/or methacrylate.
4. A contact lens according to claim 3, wherein said treatment comprises reaction of the lens surface with a polyol of the formula $R_1(OH)_n$, where R_1 is a substituted or unsubstituted alkyl, and n is an integer of at least 2.
5. A contact lens according to claim 4, wherein said polyol is selected from the group consisting of ethylene glycol, glycerine, and mixture thereof.
6. A contact lens according to claim 2, wherein said treatment comprises reacting onto said lens surface, by radiation-initiated reaction, hydroxy acrylic monomer.

7. A contact lens according to claim 6, wherein said hydroxy acrylic monomer is hydroxyalkyl acrylate and/or methacrylate.

8. A contact lens according to claim 7, wherein said radiation is electromagnetic radiation.

9. A contact lens according to claim 7, wherein said radiation is γ -ray or UV.

10. A contact lens according to claim 7, wherein said radiation is selected from the group consisting of electron beam, electrical discharge and radio frequency.

11. A contact lens according to claim 7, wherein said polymerizable vinylic siloxane monomer is γ -tris(trimethylsiloxy)silylpropyl methacrylate and wherein said hydrophilic vinylic monomer is N,N-dimethylacrylamide.

12. A contact lens according to claim 3, wherein said hydroxyalkyl acrylate and/or methacrylate is selected from the group consisting of 2-hydroxyethyl methacrylate and glyceryl methacrylate.

13. A contact lens according to claim 12, wherein said polymerizable vinylic siloxane monomer is γ -tris(trimethylsiloxy)silylpropyl methacrylate and wherein said hydrophilic vinylic monomer is N,N-dimethylacrylamide.

14. A contact lens according to claim 7 wherein said treatment produces on said lens surface a thin coating consisting essentially of poly(hydroxy alkyl acrylate and/or methacrylate).

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15. A contact lens according to claim 14 wherein said poly(hydroxy alkyl acrylate and/or methacrylate) is poly(2-hydroxyethyl acrylate and/or methacrylate).

16. A contact lens according to claim 11 wherein said treatment produces on said lens surface a thin coating consisting essentially of poly(hydroxy alkyl acrylate and/or methacrylate).

17. A contact lens according to claim 16 wherein said poly(hydroxy alkyl acrylate and/or methacrylate) is poly(2-hydroxyalkyl acrylate and/or methacrylate).

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US90/05032

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5): C08F: 30/08, 230/08; C08J 3/28

U.S.CI.: 264/1.1, 351/160H; 522/99; 523/107; 525/326.5, 384; 526/379

II. FIELDS SEARCHED

Minimum Documentation Searched⁴

Classification System	Classification Symbols
U.S.	264/1.1; 351/160H; 522/99; 523/107 525/326.5, 384 526/279
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁵	

III. DOCUMENTS CONSIDERED TO BE RELEVANT¹⁴

Category ⁶	Citation of Document, ¹⁴ with indication, where appropriate, of the relevant passages ¹⁵	Relevant to Claim No. ¹⁴
X	US, A, 4,099,859 (MERRILL) 11 July 1978,	1-10, 13, 17
Y	see example II, III in particular for glycol.	11-12
A	US, A, 4,259,467 (KEOGH et al.) 31 March 1981, see entire document.	1-17
X	US, A, 4,260,725 (KEOGH et al.) 07 April 1981, see entire document.	1-3, 12
A	US, A, 4,487,905 (Mitchell) 11 December 1984, see entire document.	1-17
A	US, A, 4,734,475 (GOLDENBERG et al.) 29 March 1988, see entire document.	1-17

* Special categories of cited documents:¹³

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search⁸

15 November 1990

Date of Mailing of this International Search Report⁹

25 JAN 1991

International Searching Authority¹⁰

ISA/US

Signature of Authorized Officer¹⁰

Herbert J. Lilling
Herbert J. Lilling

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

A	US, A, 4,780,510 (UEMIYA et al.) 25 October 1988, see entire document.	1-17
X	US, A, 4,861,840 (LIM et al.) 29 August 1989, see column 4, line 41-52.	1-3,6-10, 14,15
A,P	US, A, 4,920,184 (SCHAFFER et al.) 24 April 1990, see entire document.	1-17

V. OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE¹

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. Claim numbers _____, because they relate to subject matter¹ not required to be searched by this Authority, namely:

2. Claim numbers _____, because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out¹, specifically:

3. Claim numbers _____, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING²

This International Searching Authority found multiple inventions in this international application as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

- The additional search fees were accompanied by applicant's protest.
- No protest accompanied the payment of additional search fees.